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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,306	11/24/2003	Carl Frederick Edman		9308
<div>Carl Edman Suite 152 11772 Sorrento Valley Road San Diego, CA 92121</div>				
			<div>EXAMINER HOLMES, REX R</div>	
			<div>ART UNIT 3762</div>	<div>PAPER NUMBER</div>
			<div>MAIL DATE 06/11/2007</div>	<div>DELIVERY MODE PAPER</div>

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/722,306	<b>Applicant(s)</b> EDMAN ET AL.	
	<b>Examiner</b> Rex Holmes	<b>Art Unit</b> 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) 1-20 and 28-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-27 and 37-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/17/04; 1/10/05; 3/9/07</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of claims 21-27 in the reply filed on 3/9/07 is acknowledged.
2. Claims 1-20 and 28-36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 3/9/07.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:  

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 21-27 and 37-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Claims 21-27 and 37-47 are rejected, as they are indefinite for combining two statutory classes. Claim 21-27 is directed to an apparatus while claims 37-47 are directed toward a method of using the device. Claims 21-27 define the device and claims 37-47 define where the device is to be implanted and the device's purpose. Although claims 37-47 state device in their preamble they are clearly directed toward a method of using the device. It is suggested that claims 37-47 are re-written in functional language so that they are directed toward an apparatus claim and not a method claim. An example would be to change claim 46 to, "... wherein the device is adapted to sample bio fluids..."

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6. Claim 21 is vague as a device can not claim connection to a human body. It is suggested to use something similar to, "first surface adapted to contact tissue".
7. Claim 21 is incomplete for omitting an element to produce the time dependent signal. It is unclear whether this is being positively recited.
8. Claims 22-24 are vague as the variation in surface charge has not been positively recited but only functionally recited and therefore the variations cannot be further limited.
9. Claim 27 is vague as no element has been set forth to deliver/produce/generate a variation or signal.
10. Claim 37 is vague as the claim does not further limit the parent claim. It is suggested to change comprises to "further comprises".
11. Claim 37 is incomplete as there is no connection between the one or more first electrodes, the one or more second electrodes, the control circuitry and the device.
12. Claim 37 is vague as a device can not claim connection to a human body. It is suggested that the applicant change "subdermally located" to "adapted to be subdermally located".
13. Claim 37 is vague as it is unclear if the electrodes are the same as the first tissue contacting surface or not.
14. Claim 37 is vague as it is unclear if the electrical current listed in lines 1-2 on page 3 of the claims is the same as signal used in claim 21.
15. Claims 40 and 41 are incomplete as there is no connection between the device and the electrodes that are not affixed to the device.

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16. Claims 40 and 41 are vague as it is unclear how the device communicates with the electrodes if they are not affixed to the device. The specification is silent as to how the device communicates with the electrodes.

17. Claim 42 is vague as it is unclear what the applicant means by "percutaneous in nature". The device is either percutaneous or not.

18. Claim 43 is vague as a device cannot claim connection to a human body. It is suggested that the applicant change "fully implanted" to "adapted to be fully implanted".

19. Claim 44 recites the limitation "semipermeable structure" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim. The term is inferentially included. It is unclear if the applicant is positively reciting the element. It is suggested to first set forth that the claim has this element before it is used.

20. Claim 45 is incomplete as there is no connection between the therapeutic agent and the device. It is unclear what part of the device delivers the therapeutic agent.

21. Claim 46 is incomplete as there is no connection between the sampling fluids and the device. It is unclear what part of the device samples the biofluids. The device does not state that it has a means for sampling fluid.

***Claim Rejections - 35 USC § 102***

22. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

23. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

24. Claims 2-27, 37-43, and 45-47 are rejected under 35 U.S.C. 102(e) as being anticipated by Kroll et al. (U.S. Pat. 7,203,550 hereinafter "Kroll").

25. Regarding claims 21, 25-27, 37-43, and 45-47, Kroll discloses an implantable device with a current for fighting infection, wherein a current of 10-100mA/cm<sup>2</sup> is provided to allow antibiotics to penetrate a biofilm and destroy bacteria (Col. 1, ll. 54-58). Kroll discloses a fully implantable system inserted through the vasculature, with one electrode located in right atrium and one located in the right ventricle (Col. 2, ll. 5-11). Kroll further discloses that the device works in conjunction with antibiotics (Col. 11, ll. 47-49).

26. Regarding claims 22-24, Kroll discloses the claimed invention as described in detail above, but Kroll fails to disclose that cells are migrated and that those cells are endothelial or fibroblast cells. Kroll discloses the current density that is the same as the current density disclosed in the application, so it be inherent that the Kroll invention would cause cell migration since the values are similar and would cause migration of both endothelial and fibroblast cells. In addition, it is noted that this variation has not been positively recited.

27. Regarding claims 40 and 41, since the specification is silent as to how the device communicates with the electrodes if they are not affixed to the device the examiner is taking the position that the electrodes are connected remotely to the device. In this

case the electrodes of Kroll are remotely connected to the device and thus anticipate claims 40 and 41.

28. Regarding claim 42, the device of Kroll is capable of being attached outside of the body and have the leads implanted.

29. Regarding claim 46, the electrodes of Kroll are capable of being removed from the body and have biofluids sampled from them.

***Claim Rejections - 35 USC § 103***

30. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

31. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

32. Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kroll.

33. Regarding claim 44, Kroll discloses the claimed invention except for the electrode being separated from tissue by a semipermeable layer. It would have been obvious to

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one having ordinary skill in the art at the time the invention was made to modify the implantable device with a current for infection control in combination with an injected antibiotic as taught by Kroll, with electrodes coated in antibiotics since it was known in the art that lead electrodes covered in a semipermeable layer of an antibiotic, provide direct placement of an antibiotic near implantation sites to fight infection as opposed to injected antibiotics that take time to get to the implantation site.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rex Holmes whose telephone number is 571-272-8827. The examiner can normally be reached on M-F 8:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Rex Holmes  
Examiner  
Art Unit 3762



George Evanisko  
Primary Examiner  
Art Unit 3762

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